

Final report → When + where does info put in notes at lab level approach.

Current Data Review & Approval Guidelines for Analytical Testing

Test (number of reps)	Technician			Technical Leadership (TL)		
	Responsibilities for reviewing test results	Criteria for reviewing, rejecting, & rechecking	Requirements for recording data rejection	Responsibilities for reviewing test results	Criteria for approving, rejecting, & rechecking	Requirements for recording data rejection
<ul style="list-style-type: none"> • FTC-Nic (8,16) • FTC-H₂O (8,16) • Rotary Nic (2,4) • Rotary H₂O (2,4) • Filtrona Nic (8,16) • Filtrona H₂O (8,16) 	<ul style="list-style-type: none"> • PPI 095-405 • Print preliminary report • Check instrument ran properly/consistent • Check RT Diff ≤ 1.00 min • Check ISTD <i>via checklist</i> • Check R² range (0.9980 - 1.000) • Check Stdev blanks ≤ 0.015 • Check Conc. <i>5 in UCL adn</i> • Ckstd# 3 plotted CC and within UCL & LCL • Samples properly barcoded • Data values for all samples • Negative H₂O values (if below lowest Std edited to 0.001 • Commit Data <p><i>All in PPT & straight forward</i></p>	<ul style="list-style-type: none"> • If questionable criteria from previous column warrants rerun sample(s); reprocess data • If still out - notify TL • Reject if assignable cause: broken test tube, equipment malfunctioned, operator technique • N.D. set to missing • If missing samples (test tubes from smoke lab) set Nic & H₂O to missing 	<ul style="list-style-type: none"> • Enter in computer notes editing • Notify TL if retesting is necessary 	<ul style="list-style-type: none"> • Review only results not automatically approved by computer (Status 50 report) • Check outlier has run • Assure there is data for all test • Assure correct number of values • Review average, SD, and number of outliers or rejected data in accordance with guideline criteria. <p><i>Accepted for limits for differences</i></p>	<ul style="list-style-type: none"> • Investigate if higher than acceptable criteria or data is missing • Investigate if H₂O SD > 0.5 • Approve data if check of all smoke parameters follows the trends of TPM and Puff count • Approve data if check of Instrument and control charts are okay • Approve Rotary Nic/Tar (2 values difference between two values ≤ 15% or 1.0 mg/cig (tar); 0.1 mg/cig (nic) which ever is greater • If rotary smoke has 4 values, use same SD criteria • If recheck necessary, notify Smoke Lab TL to set up resmoke <p><i>Will be replaced by new revised criteria based on actual data of acceptability based on Nic and Tar</i></p>	<ul style="list-style-type: none"> • Enter in computer notes editing • Record in log book if analytical reason for recheck

Checklist for determining that GC is running correctly

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*6/11 Nicotine 1ST pass SD
5/2 Menthol / No flight subjects
good data*

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Men-Smoke (8)	<ul style="list-style-type: none"> • PPI 095-407 • Print preliminary report • Check instrument ran properly/consistent • Check RT Diff ≤ 1.00 min • Check ISTD • Check R² range (0.9980 - 1.000) • Check Conc. • Men-TA Monitor plotted on CC and within UCL & LCL • Samples properly barcoded • Proper Multiplier • Data values for all samples • Commit Data <p><i>Set Men TPM and PC to reflect</i></p>	<ul style="list-style-type: none"> • If questionable criteria from previous column warrants rerun sample(s); reprocess data • If still out - notify TL • Reject if assignable cause: broken test tube, equipment malfunctioned, operator technique • N.D. set to missing • Missing samples (test tubes from smoke lab) set Men to missing 	<ul style="list-style-type: none"> • Enter in computer notes editing • Notify TL if retest is necessary 	<ul style="list-style-type: none"> • Review only results not automatically approved by computer (Status 50 report) • Check outlier has run • Assure there is data for all test • Assure correct number of values • Review average, SD, and number of outliers or rejected data in accordance with guideline criteria. <p>If recheck necessary, notify Smoke Lab TL to set up resmoke</p>	<ul style="list-style-type: none"> • Investigate if higher than acceptable criteria • Approve data if check of all smoke parameters follows the trends of TPM and Puff count • Approve data if check of Instrument, control charts, and multipliers are okay 	<ul style="list-style-type: none"> • Enter in computer notes editing • Record in log book, if analytical reason for recheck <p><i>Is that since necessary in 70's putting in notes editing.</i></p>
Menthol in Filler (2) Menthol in Plug (2) Menthol on Foil (3)** Total menthol (1) Flt-TA (1) Flt-TAI (1)	<ul style="list-style-type: none"> • PPI 095-410 and PPI 095-420 • Print preliminary report • Check instrument ran properly/consistent • Check RT Diff ≤ 1.00 min • Reject if assignable 	<ul style="list-style-type: none"> • If questionable criteria from previous column warrants rerun sample(s); reprocess data • If still out - notify TL 	<ul style="list-style-type: none"> • Enter in computer notes editing • Notify TL if retesting is necessary 	<ul style="list-style-type: none"> • Review only results not automatically approved by computer (Status 50 report) • Check outlier has run • Assure correct 	<ul style="list-style-type: none"> • No set criteria • Approve, if process is in control, and samples with more than one value, the values are close to the same proximity • **Has SD criteria to follow 	<ul style="list-style-type: none"> • Enter in computer notes editing

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Flt-TAO (1)	<ul style="list-style-type: none"> Check ISTD Check R^2 range (0.9980 - 1.000) Check Conc. Men-TA Monitor plotted on CC and within UCL & LCL Samples properly barcoded Proper Multiplier Data values for all samples Commit Data 	<p>cause: broken test tube, equipment malfunctioned, operator technique</p> <ul style="list-style-type: none"> N.D. set to missing 		<p>number of values</p> <ul style="list-style-type: none"> Review average, SD, and number of outliers or rejected data in accordance with guideline criteria. <p><i>Review</i></p>		
CO (2)	<ul style="list-style-type: none"> Ensure Equipment runs properly/consistent Monitor run plotted on CC & within limits Ensure proper number of values 	<p>PPL095-205</p> <ul style="list-style-type: none"> Samples with 4.0 mg/cig or less tar level - difference \geq 0.7 mg/cig, recheck Samples greater than 4.0 mg/cig tar level - difference \geq 1.0 mg/cig, recheck Reject if assignable cause: defective cigt, operator technique, equipment malfunction <p><i>Too many rechecks</i></p>	<ul style="list-style-type: none"> Log recheck in log book Enter in computer notes editing 	<ul style="list-style-type: none"> Review samples from Status 50 report <p><i>All (1) come up to be reviewed & approved.</i></p>	<ul style="list-style-type: none"> Approve samples with 4.0 mg/cig or less tar level - difference \leq 0.7 mg/cig, else recheck Approve samples greater than 4.0 mg/cig tar level - difference \leq 1.0 mg/cig, else recheck <p><i>Guidelines</i></p> <ul style="list-style-type: none"> Average \pm 1.0 mg/cig from tar spec (if available) or smoked tar value of sample (preferred) <p><i>Need better guidelines</i></p>	<ul style="list-style-type: none"> Enter in computer notes editing Recheck barcode taken to GPI Tech

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